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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/629,108 | 07/28/2003 | Kazuo Koyama | 03338CIP/HG | 6344 |
| 1933 | 7590 | 01/03/2006 | EXAMINER | |
| FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 220 Fifth Avenue 16TH Floor NEW YORK, NY 10001-7708 | | | SOLOLA, TAOFIQ A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,108

Applicant(s)

KOYAMA ET AL.

Examiner

Taofiq A. Solola

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The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 46-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 93-118 is/are rejected.
- 7) ☐ Claim(s) 46-92 and 119 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). -
- See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 46-119 are pending in this application.

Claims 93-118 are drawn to non-elected invention.

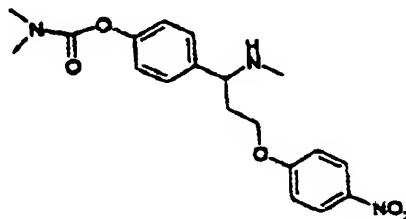
Claims 1-45 are cancelled.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/16/05 has been entered.

RESTRICTION REQUIREMENT

The election of group I, claims 46-92, 119 in the paper filed 12/20/04 is hereby



acknowledged. Applicant elects the following compound:

wherein in formula 1, R1 is dimethylamino, X1 and X2 are each oxygen, Ra and R2 are each H, R3 is methyl, A is $-C_2H_4-$, E is oxygen and Arom is phenyl substituted at position 4 by NO_2 .

Therefore, claims 46-92, 119 are being examined in part subject to the election made by applicant.

Status of Claims

The Office has reviewed the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar

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thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention encompasses all compounds within the scope of the claims, which fall into the same class and subclass as the elected compound (or set of compounds), but may also include additional compounds, which fall in related subclasses. Examination of the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification results in the following:

In formula 1, A, R1-R4 and X1 are as defined in claim 46; X2 is oxygen and attached at position C4 of the phenyl ring; Ra is as defined in claim 46 but do not combine together with R2; E is O, S or NR4; and Arom is optionally substituted phenyl. As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 46-92, 119 are withdrawn from further consideration by the Examiner, under 37 CFR § 1.142(b), as being drawn to non-elected subject matters. The withdrawn compounds are patentably distinct from the elected invention as they differ in structure and element and would require a separate search. In addition, a reference, which anticipates the elected invention, would not render obvious the non-elected subject matter.

In an interview between the Examiner and Applicant's representative on/about 11/9/05 Applicant's representative agreed to amend claims 46-92, 119 as suggested for allowability above. Therefore, the restriction of claims 93-118 is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 93-118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 93-118 lack adequate support in the specification. Claims 93-101 are drawn to method of inhibiting acetylcholinesterase and selective serotonin uptake. This is not a practical utility except one reads the specification into the claims contrary to the Office practice. Such would also make the claims substantial duplicates of claims 102-118. Claims 93-101 are attempts by Applicant to claim method of treating diseases that may be discovered in the future arising from inhibition of acetylcholinesterase and selective serotonin uptake. Therefore, they are deemed reach-through claims. By deleting the claims the rejection would be overcome.

In support of claims 102-118, the specification, page 274, reads as follows:

Compounds of the present invention exert inhibitory activities towards both acetylcholinesterase activity and selective serotonin re-uptake, and are useful as preventative and/or therapeutic agents for Alzheimer's disease, depression, Huntington's chorea, Pick disease, tardive dyskinesia, obsessive-compulsive disorder, or panic disorder.

Above assertion is not supported in the specification with either biological assays or previous studies published in journal articles. Applicant must submit published results of scientific studies establishing conclusive evidence between inhibition of acetylcholinesterase and selective serotonin uptake and the claimed utilities. It is not clear from the specification if "Test" compounds in table 6, pages 270-271, are the same as example compounds. Applicant must admit on record that the compounds are in fact the same.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 93-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For reasons set forth above under 35 USC 112, first paragraph, claims 93-118 are indefinite. See the Examiner's suggestion above.

Objection

Claims 46-92, 118 are objected to for containing non-elected subject matter. To place the application in condition for allowance, applicant must amend the claims as set forth above under Status of Claims.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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November 14, 2005


TAOFIQ SOLOLA
PRIMARY EXAMINER